RECORD AND BRIEFS

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Nos. 15-1039 and 15-1195

In the Supreme Court of the United States

SANDOZ INC.,
Petitioner,
v.
AMGEN INC., ET AL.,
Respondents.

AMGEN INC., ET AL.,
Petitioners,
v.
SANDOZ INC.,
Respondent.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR ABBVIE INC. AS AMICUS CURIAE IN SUPPORT OF AMGEN INC., ET AL.

MELISSA ARBUS SHERRY
Counsel of Record
GREGORY G. GARRE
MICHAEL A. MORIN
CASEY L. DWYER
ALEXANDRA SHECHTEL
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2200
melissa.sherry@lw.com
Counsel for Amicus Curiae AbbVie Inc.

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INTERESTS OF AMICUS CURIAE[1]

AbbVie Inc. is an innovative biopharmaceutical company that discovers, develops, and markets drugs for the treatment of many diseases, including HIV, hepatitis C, cancer, multiple sclerosis, Parkinson's disease, and immunological diseases. One of AbbVie's drugs, HUMIRA® (adalimumab), was the first fully-human antibody to be approved by the Food and Drug Administration (FDA). HUMIRA® has been used to treat over one-million patients suffering from diseases as diverse as rheumatoid arthritis, psoriasis, and Crohn's disease.

HUMIRA® is one of a growing category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. Biologics can treat diseases very effectively, but are difficult to develop and manufacture because of their complexity. AbbVie's clinical research on HUMIRA® has included over 100 clinical trials and resulted in FDA approval for the treatment of ten different diseases. While Sandoz, Inc. and several of its amici call out HUMIRA® as an example of the high cost of biologics and emphasize how expensive it is to develop a *biosimilar* product, those expenditures pale in comparison to the expense and risk AbbVie took on in developing its original, pioneering biologic.

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[1] The parties have consented to the filing of this amicus brief. No counsel for any party authored this brief in whole or in part; and no such counsel or any party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than amicus and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

HUMIRA® is the subject of biosimilar applications under the Biologics Price Competition and Innovation Act of 2009 (BPCIA), Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-21 (2010). On September 23, 2016, Amjevita, the first biosimilar for HUMIRA®, was approved by the FDA. Amjevita has not been commercially released; it is currently the subject of patent litigation, and no notice of commercial marketing has yet been provided. Amjevita is one of only four biosimilars that have been approved by the FDA to date. Many other companies, including Sandoz, have announced that they will also be seeking FDA approval for biosimilars to HUMIRA®. Moreover, AbbVie has developed and will continue to develop new biologics that likely will be the subject of biosimilar applications under the BPCIA. AbbVie thus has a significant interest in ensuring a fair system of resolving patent disputes surrounding the approval of biosimilar products, as well as real-world experience operating under the BPCIA notice-and-exchange procedures at issue in this case.

INTRODUCTION AND SUMMARY OF ARGUMENT

There are two overarching issues in this case: (1) what the BPCIA requires in terms of the notice-and-exchange process, and (2) what a reference product sponsor can do if a biosimilar applicant fails to comply with those requirements. The answer to the first question is straightforward: at the front end, applicants are required to provide their abbreviated Biologics License Applications (aBLA) and manufacturing information to the reference product sponsor; at the back end, they are required to provide 180 days' notice of commercial marketing after FDA

licensure. The second question is not properly presented and need not be decided by the Court.

On the first question, Sandoz and its amici argue that Congress created an entirely discretionary notice-and-exchange process whereby biosimilars can opt-out at any time and provide "notice" (if at all) months or even years before any possible launch. Sandoz tries to portray that scheme (which bears no resemblance to the one Congress actually enacted) as entirely reasonable and consistent with what "rational" actors would do. But Sandoz's account is inconsistent with the FDA approval process, contradicted by real-world events, and premised on potential exceptions to a generally applicable rule. In the end, a discretionary "notice" of commercial marketing that has no temporal nexus to actual commercial marketing is the functional equivalent of no notice at all.

On the second question, Sandoz and its amici ask this Court to hold that, where an applicant violates the BPCIA's notice-and-exchange provisions, there is no *federal* private right of action to enforce the statute. But that question is not presented here: Amgen, Inc. brought only *state*-law claims to enforce the BPCIA. Thus, the only salient question that could be before the Court is whether Amgen's state-law claims are preempted by the BPCIA. Sandoz, however, has expressly disavowed any preemption defense and, accordingly, has waived that argument, which leaves this Court with an exceedingly unsuitable vehicle to resolve the enforcement question. To the extent the Court wishes to decide the issue at all, preemption is the correct framework and Amgen's state-law claims are not preempted. But the more prudent course would be to affirm Amgen's interpretation of the

statute and leave the means of enforcement for another day.

ARGUMENT

I. SANDOZ'S ACCOUNT OF HOW THE BPCIA SHOULD WORK IS INCOMPLETE AND INCONSISTENT WITH THE ACTUAL STATUTE

This Court should affirm the Federal Circuit's unanimous holding that the 180-day notice of commercial marketing cannot be provided before FDA licensure. Amgen's brief persuasively explains why the plain text, statutory structure, and legislative history compel that reading. *See* Amgen Br. 27-42.[2] That should be the end of the analysis.

Sandoz and its amici, however, expend considerable energy painting a misleading picture of the patent litigation and FDA approval process undergirding the BPCIA. From the information available to reference product sponsors during the FDA approval process, to when biosimilars would choose to provide commercial notice if given such discretion, to what patents remain to be litigated during the 180-day notice period, the topside briefs tell an incomplete story at best. To place the Court's statutory interpretation task in its proper context, this brief addresses just a few of the many holes in that tale. In the end, congressional intent remains the touchstone and provides the answer:

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[2] For example, 42 U.S.C. § 262(*l*)(8)(A) critically refers to the biological product "licensed" under subsection (k), not the biological product "that is the *subject of*" an application under subsection (k), as elsewhere in the statute when Congress so intended. *See* Amgen Br. 28-31.

Congress created a detailed, sequential, and mandatory notice-and-exchange process to streamline patent litigation before commercial launch.[3]

A. The BPCIA Is In Its Infancy

In evaluating Sandoz's speculation about what stakeholders will and will not do if given the choice, it is important to remember that the BPCIA is a new statutory scheme. It was enacted as part of the Patient Protection and Affordable Care Act in 2010. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). And the FDA did not issue its first guidance on the BPCIA biosimilar pathway until 2012. Leah Christl, U.S. Food and Drug Administration, *FDA's Overview of the Regulatory Guidance for the Development and Approval of Biosimilar Products in the US* 15, https://tinyurl.com/hmmpnv3 (last visited Mar. 15, 2017).

To the best of AbbVie's knowledge, the first biosimilar application was not submitted to the FDA until 2014.[4] From 2014 until the Federal Circuit's July 21, 2015 decision in this case, the FDA received only five known applications: from Sandoz (for Amgen's

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[3] While not the primary focus of this brief, AbbVie also agrees with Amgen that the Federal Circuit was wrong to hold that Section 262(*l*)(2)(A) is optional. The statutory command that a biosimilar applicant "shall" provide its application and manufacturing information to the reference product sponsor is mandatory, as even the United States concedes. *See* U.S. Amicus Br. 16.

[4] Because the aBLAs are not public (*see infra* at 8), only the FDA knows for certain what applications have been filed and when.

Neupogen®), Celltrion (for Janssen's Remicade®), Apotex (for Amgen's Neulasta® and Neupogen®), and Hospira (for Amgen's Epogen®). *See* Addendum A (chart detailing these subsection (k) applications with corresponding cites). Based on publicly available information, it appears that a total of between one and two dozen subsection (k) applications have been submitted to the FDA.[5]

To date, the FDA has approved only four biosimilars through the subsection (k) abbreviated pathway:

- Sandoz's Zarxio, a biosimilar of Amgen's Neupogen (approved March 6, 2015);[6]
- Celltrion and Pfizer's Inflectra, a biosimilar of Janssen's Remicade (approved April 5, 2016);[7]

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[5] Eastern Research Group, Inc., *Review of Biosimilar Biologic Product Applications: Study of Workload Volume and Full Costs*, Final Results Report 4 (Feb. 24, 2016), https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM488846.pdf (seven applications filed through 2015); Biosimilar Review & Report, *US 351(k) Biosimilar Filings: Biosimilar Drug Status In The US: FDA Filing Dates And Actions* (2017), https://biosimilarsrr.com/us-biosimilar-filings/ (counting fourteen public applications).

[6] News Release, U.S. Food & Drug Administration, *FDA approves first biosimilar product Zarxio* (Mar. 6, 2015), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm.

[7] News Release, U.S. Food & Drug Administration, *FDA approves Inflectra, a biosimilar to Remicade* (Apr. 5, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm.

- Sandoz's Erelzi, a biosimilar of Amgen's Enbrel (approved August 8, 2016);[8] and
- Amgen's Amjevita, a biosimilar of AbbVie's HUMIRA® (approved September 23, 2016).[9]

And for the last 20 months, biosimilar applicants and reference product sponsors have operated under the Federal Circuit's decision in this case. In fact, the *only* biosimilar approved by the FDA before the Federal Circuit's decision was the one at issue here.

Accordingly, virtually all of the actual examples Sandoz and its amici point to played out in a world where the Federal Circuit's interpretation of the BPCIA was the controlling law. Any predictions about "rational" party behavior based on this exceedingly small and skewed data set are thus of limited value, and give no insight as to what biosimilar applicants will do if the commercial-marketing notice requirement is marginalized or effectively nullified.

B. The BPCIA In Practice Bears Little Resemblance To Sandoz's Account

There are many flaws in Sandoz's story, but three are of particular note: (1) Sandoz's claim that the Court should not be concerned about the lack of transparency under its approach because all relevant information

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[8] News Release, U.S. Food & Drug Administration, *FDA approves Erelzi, a biosimilar to Enbrel* (Aug. 30, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm518639.htm.

[9] News Release, U.S. Food & Drug Administration, *FDA approves Amjevita, a biosimilar to Humira* (Sept. 23, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm522243.htm.

about the biosimilar application is publicly available; (2) Sandoz's claim that post-licensure notice of commercial marketing is meaningless whereas pre-licensure notice is meaningful; and (3) Sandoz's claim that the possibility that there will be no patents left to litigate during the 180 days makes post-licensure notice problematic. Aside from their speculative nature, Sandoz's claims are refuted by real-world examples and inconsistent with the framework Congress envisioned and enacted.

1. Sandoz first claims that a "sponsor would know about the filing of [a biosimilar] application even when the applicant did not provide a copy." Sandoz Br. 48. But it is undisputed that the aBLA is neither publicly filed nor otherwise available to the reference product sponsor. The same is true of the manufacturing information that the BPCIA directs "shall" be provided with the aBLA. 42 U.S.C. § 262(*l*)(2)(A).

Sandoz's contention, instead, is that a sponsor would (or could) cobble together sufficient information from SEC filings, press releases, clinical trial data, and FDA public meetings to conclude that a filing had (likely) occurred. Sandoz Br. 48-51. Even taking that infirm assumption as true, none of those sources would include the content of the aBLA itself, let alone the manufacturing information. Thus, the sponsor would know nothing about the manufacturing of the product, its formulation, or its indicated uses—all of which are paramount in determining whether the sponsor's patent rights have been trespassed upon.

Moreover, the detailed notice-and-exchange process Congress envisioned looks nothing like the haphazard and piecemeal process Sandoz now advocates:

- The BPCIA: the biosimilar applicant "shall" provide the aBLA and manufacturing information to the sponsor within 20 days. 42 U.S.C. § 262(*l*)(2)(A).
- Sandoz: the sponsor should instead scour a variety of different sources to try to divine whether an aBLA had been filed and patch together a complaint based on the minimal information contained in those sources.

Congress plainly intended there to be a more transparent, informed, and streamlined approach to early patent litigation. *See, e.g., Biologics and Biosimilars: Balancing Incentives for Innovation: Hearing Before the Subcomm. on Courts & Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 9 (2009) (statement of Rep. Anna G. Eshoo) (the proposed notice-and-exchange provisions "will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product"); *id.* at 8-9 (explaining the bill's "simple, streamlined patent resolution process"); Letter from C. Landis Plummer, Acting Sec'y, FTC, to Rep. Frank Pallone, Jr. 6-9 (May 2, 2008) (advising that biologics legislation includes a "pre-marketing patent litigation process" that "involve[s] private exchange of patent information").

2. Sandoz next claims that the "Federal Circuit's rule permitting 'notice' only after FDA approval also deprives Section 262(*l*)(8)(A) of any *notice* function." Sandoz Br. 41. The reason, according to Sandoz, is that "the FDA itself provides public notice that a biosimilar may be commercially marketed." *Id.* In other words, Sandoz views FDA approval as the equivalent of notice of commercial marketing. There are several problems

with this approach and, in the end, it is Sandoz's interpretation that deprives Section 262(*l*)(8)(A) of any true "notice" function.

First, Sandoz's argument conflates the product submitted as part of the aBLA with the final product approved by the FDA, and elides important distinctions between the two. But things can and do change between the filing of the aBLA and approval of the final product. *See* Amgen Br. 24 (noting that Sandoz's application was amended 30 times). For example, the indicated uses could be modified, either in terms of the diseases to be treated or the regimen used to treat those diseases, as could the formulation, delivery system, or manufacturing process. If biosimilars could launch immediately upon FDA approval, there would be no time to litigate patent infringement issues implicated by the approved biosimilar but not apparent from the face of the aBLA submitted many months, if not years, prior.

As Amgen explains, the BPCIA contemplates and provides for two phases of patent litigation. In the first phase, the parties "identify patent claims that can meaningfully be adjudicated or otherwise resolved before the FDA determines what, precisely, will be licensed." Amgen Br. 15. In the second phase, the parties can litigate the remaining patent claims including both (1) those identified in the notice-and-exchange process but not chosen for phase-one litigation, and (2) new patents issued to or exclusively licensed to the reference product sponsor after providing the initial list. *Id.* Sponsors need the 180-day notice window to compare the approved product to the aBLA, identify any remaining patent disputes, and (if needed) to file a preliminary injunction.

Second, FDA approval does not necessarily mean that commercial launch will immediately follow. Rather, a biosimilar might choose to wait for a period of time after FDA approval before giving commercial-marketing notice in order to delay litigating the remaining patents. Unlike Sandoz's examples, this is not fanciful speculation; it has *actually* occurred. As noted above, Amjevita, Amgen's biosimilar for HUMIRA®, was approved by the FDA on September 23, 2016. *See supra* at 7 n.9. Yet Amgen (the biosimilar applicant in that case) still has not given notice of commercial marketing nor has it launched. As such, AbbVie cannot yet assert its phase-two patents. The Amjevita situation thus proves unequivocally that a post-licensure notice provision is *not* duplicative of the announcement that the FDA has issued a license.

Third, it is Sandoz's reading that deprives Section 262(*l*)(8)(A) of a true "notice" function. Early "notice" of commercial marketing—months or even years before FDA approval—is no notice at all. At that point, nobody knows what (if anything) will ultimately be approved and marketed or when (or if) such marketing will occur. Indeed, as Amgen explains, "[i]t is not clear how an applicant can provide 'notice' of marketing when a condition precedent to marketing—namely, licensure—is wholly dependent on FDA action." Amgen Br. 33.

If the sponsor filed a motion for a preliminary injunction under Section 262(*l*)(8)(B) at that time, before launch is imminent (or even likely), the case for infringement and irreparable harm would look dramatically different. The United States goes so far as to claim that the preliminary injunctive relief central to the Section 262(*l*)(8) notice provision is not available

at all until launch is "imminent." U.S. Amicus Br. 18; *id.* at 13 ("Declaratory relief is the only relief available in such an action brought any significant amount of time before a biosimilar's commercial marketing."); *id.* at 23-24 & n.7 ("[A] sponsor cannot bring an artificial-infringement action for [injunctive] relief any significant amount of time before a biosimilar's commercial marketing. . . . [S]uch traditional equitable relief would be available only when [manufacture, use, or sale] are sufficiently real and imminent."). But that only proves that the premature "notice" of commercial marketing advocated by Sandoz cannot possibly be correct. After all, under Sandoz's approach, sponsors would never know that launch is imminent enough to warrant injunctive relief until the launch has already occurred. And that flat-out defeats the purpose of providing for orderly patent litigation before commercial launch. The BPCIA sets forth a process of post-licensure notice followed by a pre-launch preliminary injunction on a concrete dispute (where appropriate), not premature "notice" with no ability to enjoin launch followed by a rush to the courthouse to get a last-minute temporary restraining order upon announcement of FDA approval. *See* Amgen Br. 38-42.

Sandoz never explains what "notice" function pre-licensure notice as early as the day the aBLA is filed could possibly serve. If the goal is to litigate all patent disputes (then-existing and apparent from the aBLA) before FDA approval, the biosimilar applicant already has that power. It can simply choose to litigate *all* such patent claims in phase one, under Sections 262(*l*)(3)(B) and 262(*l*)(5)(A). The notice instead serves a different purpose: to permit time to litigate remaining patent disputes based on the final, approved

product when launch is fairly imminent. "Notice" that a biosimilar applicant may someday market a biosimilar if licensed at some unknown date in the future is meaningless. In reality, it is no notice at all.

Sandoz's response: no rational biosimilar applicant would provide such early notice. Specifically, Sandoz speculates that an applicant would not "behave so irrationally—providing its application to the sponsor (thus triggering the process meant to narrow and allow it to control the scope of immediate litigation) while simultaneously eliminating the value of that narrowing process by providing its notice of commercial marketing (thus inviting immediate litigation on any and all patents)." Sandoz Br. 38-39.

But Sandoz's speculation is demonstrably false. This "irrational[]" hypothetical has in fact occurred in the *majority* of cases to date. AbbVie is aware of only five total instances in which a biosimilar applicant has provided *any* notice of commercial marketing. In two (Hospira's biosimilar of Epogen and Apotex's biosimilar of Neupogen), the applicant provided the aBLA pursuant to Section 262(*l*)(2)(A) and then provided Section 262(*l*)(8)(A) notice of commercial marketing just five or six weeks later. *See* Addendum A. And in two others (Celltrion's biosimilar of Remicade and Apotex's biosimilar of Neulasta), the applicants gave their Section 262(*l*)(8)(A) notices less than four months after providing the aBLAs. *Id.* That is, in all four of these examples, the applicant gave notice of commercial marketing very soon after providing the aBLA, long before the notice-and-exchange processes were finished, and many months (or even years) before any prospect of actual launch. Indeed, nearly two years have since passed and three

of these biosimilars still have not been approved by the FDA. *Id.*

In short, true "notice" of commercial marketing can occur only when commercial marketing is reasonably imminent and the product to be marketed is actually known—*i.e.*, after FDA licensure.

3. Sandoz and its amici also repeatedly rely on the same two refrains: (i) post-licensure notice is an unwarranted extension of the 12-year period of exclusivity, and (ii) post-licensure notice will delay launch by 180 days even when there are no remaining patents to be litigated. *See, e.g.*, Sandoz Br. 6-7, 30, 33, 39-40, 56-60; U.S. Amicus Br. 29, 32; Apotex Amicus Br. 11, 14, 19.

Amgen explains the many reasons why these concerns are unfounded. *See* Amgen Br. 52-58. For example, Sandoz itself offered a proposal during the legislative process that would have similarly delayed market entry post-licensure to allow for orderly patent litigation. *Id.* at 53-54. Specifically, Sandoz (along with its corporate parent Novartis) proposed an exclusivity period of at least 12 years, followed by a post-licensure notice period during which time the biosimilar could not launch. *Id.* What Sandoz now claims is illogical is actually a fairly close replica of the regime it proposed.

And while Sandoz suggests that the 180-day notice period will be unnecessary when there are no patents left to litigate, Amgen explains that "it will be rare that a sponsor has no patents to assert" during that 180-day window. *Id.* at 56. As AbbVie can attest, sponsors often continue to innovate, develop their products, improve manufacturing processes, and invent new methods to treat patients long after discovery of the original therapeutic molecule. Indeed, when initially

approved in 2002, HUMIRA® was only indicated for the treatment of one disease, rheumatoid arthritis. Since then, due to AbbVie's continuing innovation, the FDA has approved HUMIRA® for the treatment of *nine* additional diseases. And the Patent and Trademark Office has issued 12 new patents relevant to Amgen's biosimilar of HUMIRA® since AbbVie provided its Section 262(*l*)(3)(A) list to Amgen.

AbbVie's case against Amgen provides a useful example of the work to be done during the 180-day notice period. AbbVie identified more than 60 patents during the BPCIA patent exchange process. Compl. ¶ 39, *AbbVie v. Amgen*, No. 16-cv-00666 (D. Del. Aug. 4, 2016). After going through notice-and-exchange, Amgen limited the initial litigation to just ten patents—as was its right under the BPCIA. *See id.* ¶¶ 8, 20. Accordingly, AbbVie must now wait until Amgen provides notice of commercial marketing to bring suit on the 50+ remaining patents. Once Amgen provides that notice, AbbVie will need the 180 days to seek, if necessary, a preliminary injunction.

Even if it turns out in other cases that there ultimately are no patents left to litigate in the second phase, there is still nothing illogical about a rule that imposes a 180-day post-licensure notice period. As discussed above, sponsors still need time to assess whether the final product violates additional patents or if the infringement analysis has changed based on the final, approved product. But more fundamentally, Congress created a generally applicable rule. That a general rule may not serve the congressional purpose in *every* case does not give courts license to rewrite it. *See, e.g., Califano v. Jobst*, 434 U.S. 47, 53 (1977) ("There is no question about the power of Congress to

legislate on the basis of such factual assumptions. General rules are essential . . . [for] efficiency, even though such rules inevitably produce seemingly arbitrary consequences in some individual cases.").

* * *

In the end, Sandoz's interpretation cannot be squared with the real-world behavior of applicants or the deliberate, sequential process Congress enacted. Indeed, even Sandoz and its amici are at odds on their proposed rule. Sandoz and the United States argue that Section 262(*l*)(8)(A) notice is *only* required if the applicant engaged in the notice-and-exchange process. Sandoz Br. 61-62; U.S. Amicus Br. 32-33. Apotex argues that notice of commercial marketing is *only* required if the applicant did *not* engage in the notice-and-exchange process. Apotex Amicus Br. 23. Neither reading comports with the statute as written; the notice of commercial marketing is mandatory in all circumstances. Congress certainly believed that the parties would engage in the notice-and-exchange process, since that is mandatory too. But either way, Congress intended to give sponsors an opportunity to assess the biosimilar *as licensed*, examine their patents (litigated or otherwise), and seek a preliminary injunction before launch.

II. THIS CASE DOES NOT PRESENT ANY QUESTION ABOUT FEDERAL PRIVATE RIGHTS OF ACTION

If the Court agrees with Amgen that the notice-and-exchange provisions are mandatory and that the 180-day notice of commercial marketing can only be given after the product is licensed, it can and should stop there. For all of the focus on *federal* private

rights of action in the topside briefs, that question is not presented here: the only claims Amgen brought to enforce the BPCIA were under state law.

The question that could have been presented—*i.e.*, whether those state-law claims are preempted by the BPCIA—was neither pressed nor passed on below. Sandoz affirmatively disavowed any reliance on a preemption defense and, for that reason, the Federal Circuit declined to address that argument.

Under these circumstances, the better course is to definitively resolve the statutory interpretation question and leave the issue of enforcement for another day. That approach is especially appropriate here because the injunction Sandoz challenges expired in September 2015. *See* Amgen Br. 5. Alternatively, if the Court chooses to address enforcement, Sandoz bears the burden of proving that the California state-law claims are preempted and it cannot make that considerably more stringent showing.

A. The Enforcement Question Is Not Properly Presented

Sandoz and the United States spend a significant portion of their respective briefs arguing that there is no *federal* private right of action. *See, e.g.*, Sandoz Br. 28-29, 43-48, 53-56; U.S. Amicus Br. 20-22, 35. But they never confront the fact that Amgen brought only state-law claims to enforce the BPCIA.[10] Specifically, Amgen alleged that Sandoz had violated California's Unfair Competition Law (UCL), Cal. Bus. & Prof.

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[10] Amgen also sued for patent infringement, and later amended its complaint to include an additional claim of infringement. Those federal claims remain pending in the district court. *See* Amgen Br. 22.

Code § 17200 *et seq.*, which prohibits any "unlawful, unfair or fraudulent business act or practice," and that Sandoz's use of Amgen's property to obtain a government privilege was an illegal act of conversion under California law. *See* Compl. ¶¶ 78-106, *Amgen v. Sandoz*, No. 14-cv-04741 (N.D. Cal. Oct. 24, 2014), ECF No. 1 ("*Amgen* Compl."). This Court should not decide whether a federal private right of action exists in a case where a federal claim was never alleged. *Cf. Atl. Coast Line R.R. Co. v. Glenn*, 239 U.S. 388, 393 (1915) ("[W]e confine ourselves to the case before us" and do not decide "questions [that] are not presented by the record.").

Rather, when the operative claims arise under state law, the relevant question is whether the BPCIA somehow *preempts* state law. But that question is not presented here either. Preemption is an affirmative defense that can be waived. *See Teutscher v. Woodson*, 835 F.3d 936, 945 n.1 (9th Cir. 2016) (finding waiver of preemption defense for failure to raise in district court or on appeal); *Russian Media Grp., LLC v. Cable Am., Inc.*, 598 F.3d 302, 309 (7th Cir. 2010) ("[F]ederal preemption [is] an affirmative defense" that can be "permanently waived."); *see also Wood v. Milyard*, 566 U.S. 463, 470 (2012) ("An affirmative defense, once forfeited, is excluded from the case." (internal quotation marks, alterations, and citations omitted)).

Critically, Sandoz has never argued that Amgen's state-law claims are preempted—not in the district court, the Federal Circuit, or this Court. Pet. App. 26a n.5 ("In its cross-motion for judgment on the pleadings, Sandoz did not argue preemption as a defense to Amgen's state law claims, and thus the district court did not consider that issue."). Indeed, Sandoz

affirmatively disavowed any such argument. CAJA1854 ("We have not argued preemption of the state law claims"). Because Sandoz never argued that Amgen's state-law claims were preempted, the Federal Circuit expressly declined to pass on that question. Pet. App. 26a n.5 ("We therefore do not address preemption in this appeal."). This Court should not decide an issue that was neither "pressed [n]or passed upon" below. *Youakim v. Miller*, 425 U.S. 231, 234 (1976) (per curiam) ("It is only in exceptional cases coming here from the federal courts that questions not pressed or passed upon below are reviewed." (citation omitted)).

B. Sandoz Cannot Prove That The BPCIA Preempts Amgen's State-Law Claims

If, despite Sandoz's clear waiver, this Court nevertheless chooses to address the enforcement question, familiar preemption case law provides the appropriate framework. Take Amgen's claim under the UCL, for example. The UCL allows recovery for "unlawful" business practices that harm a competitor. Cal. Bus. & Prof. Code § 17200 *et seq.* Amgen's complaint alleges that Sandoz acted unlawfully by, among other things, failing to provide the notice of commercial marketing required by Section 262(*l*)(8)(A). *Amgen* Compl. ¶ 80. If that conduct was "unlawful" (and it was), the only question is whether the UCL claim is preempted by the BPCIA.[11] It is not.

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[11] There can be no real dispute that a violation of the BPCIA constitutes "unlawful" conduct under the UCL. *See Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 539 (Cal. 1999) ("[T]he unfair competition law's scope is broad. . . . Its coverage is sweeping, embracing anything that can properly be

1. *The existence of a federal private right of action does not control the preemption analysis*

The United States asserts that, to enforce a federal statutory provision, "Congress must itself create a cause of action" and that the absence of such a cause of action is "fatal." U.S. Amicus Br. 14, 22. But States can create claims that incorporate federal law even where Congress has not created a federal private right of action. This is a well-established proposition. In *Bates v. Dow Agrosciences LLC*, for example, the Court explained that even though a federal statute did "not provide a federal remedy to [those] injured as a result of a manufacturer's violation of [the statute's] labeling requirements, nothing in [the statute] precludes States from providing such a remedy." 544 U.S. 431, 448 (2005).

Indeed, the United States previously told this Court as much in the context of comparable UCL claims. *See* Brief of the United States as Amicus Curiae 12-15, *Rose v. Bank of Am., N.A.*, 134 S. Ct. 2870 (2014), 2014 WL 2202864 ("*Rose* Br."); Brief for the United States as Amicus Curiae 11-14, *Albertson's, Inc. v. Kanter*, 555 U.S. 1097 (2009), 2008 WL 5151069 ("*Albertson's* Br."). In *Rose*, the United States explained that a federal statute cannot "foreclose a state-law action ... without a finding that Congress intended to 'preempt' state law." *Rose* Br. 10. "'The party who brings a suit is master to decide what law he will rely upon,' and therefore may sue under state law whether or not the same allegations would support a

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called a business practice and that at the same time is forbidden by law." (citation and internal quotation marks omitted)).

federal-law cause of action." *Id.* at 14-15 (citation omitted). Whether "Congress has provided a private right of action or a private remedy *under federal law*" is a "fundamentally different question" than whether Congress has preempted state law. *Id.* at 16. Simply put, "Congress's decision not to authorize a private action under federal law" does not "preclude[] a State from creating . . . a parallel or identical private action under state law." *Id.* This is true even when the federal statute expressly *prohibits* private enforcement actions. *See Albertson's* Br. 8 ("Although 21 U.S.C. 337 precludes private actions to enforce the [Federal Food, Drug, and Cosmetic Act (FDCA)] itself, Section 337 does not prohibit private actions to enforce parallel state requirements.").

The California Supreme Court has held likewise, rejecting the argument that UCL claims are preempted even when a federal right of action was indisputably unavailable. *See, e.g., Rose v. Bank of Am., N.A.*, 304 P.3d 181, 186 (Cal. 2013) ("It is settled that a UCL action is not precluded 'merely because some other statute on the subject does not, itself, provide for the action or prohibit the challenged conduct.'" (citation omitted)), *cert. denied*, 134 S. Ct. 2870 (2014); *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1180 (Cal. 2008) ("[I]t is undisputed that section 337 [of the FDCA] bars private enforcement of the FDCA .... However, plaintiffs do not seek to enforce the FDCA. Their action is based on the violation of *state law* . . . .").

Thus, the purported absence of a federal private right of action to enforce the notice-and-exchange provisions of the BPCIA has no bearing on whether Amgen's UCL claim is preempted.

2. *Any BPCIA "remedy" is not exclusive*

Similarly, any alleged "remedy" provided by the BPCIA would not preclude UCL enforcement. Under California law, the UCL "is meant to provide remedies *cumulative* to those established by other laws, absent express provision to the contrary." *Rose*, 304 P.3d at 187 (citing Cal. Bus. & Prof. Code § 17205). Indeed, California courts "have long recognized that the existence of a separate statutory enforcement scheme does not preclude a parallel action under the UCL." *Id.* (citing *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 950 P.2d 1086, 1098-99 (Cal. 1998)). UCL remedies are unavailable *only* if the underlying "statute itself provides that the remedy is to be exclusive." *State v. Altus Fin., S.A.*, 116 P.3d 1175, 1187 (Cal. 2005).

The BPCIA does not expressly provide an *exclusive* remedy for violating the 180-day commercial notice provision. The only provision of the statute that Sandoz identifies as a "remedy" is Section 262(*l*)(9)(B), which lifts the stay on a sponsor's ability to bring a declaratory judgment action if the applicant fails to follow certain steps in the notice-and-exchange process, including by failing to provide commercial notice. That provision is hardly remedial. An applicant cannot "fail" to give notice of commercial marketing unless and until it launches its product without notice. But once the product has launched, the sponsor can bring a garden-variety patent infringement suit under 35 U.S.C. § 271 anyway. Thus, Section 262(*l*)(9)(B) imposes *no* consequence for failing to give notice.

To the extent Section 262(*l*)(9)(B) can fairly be described as a "remedy" at all, it is not exclusive. "To forestall an action under the unfair competition law,

another provision must actually 'bar' the action or clearly permit the conduct." *Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 541 (Cal. 1999). Thus, courts have generally required that the underlying statute *expressly* designate a remedy as "exclusive" in order to bar UCL relief. *Blue Cross of Cal., Inc. v. Superior Court*, 102 Cal. Rptr. 3d 615, 627 (Ct. App. 2009) ("[I]n order for a statute to deprive the city attorney of authority to sue under the UCL . . . , it must do so *expressly*."); *Stevens v. Superior Court*, 89 Cal. Rptr. 2d 370, 377 (Ct. App. 1999) (holding that relief under the UCL was not barred because the underlying statute "*does not expressly provide for exclusivity of its remedies*"); *see also People v. McKale*, 602 P.2d 731, 735 (Cal. 1979).

There is nothing in the BPCIA that so much as suggests that Congress intended Section 262(*l*)(9)(B) to be exclusive. The paragraph is entitled "Limitation on declaratory judgment action." 42 U.S.C. § 262(*l*)(9). The relevant subparagraph simply provides that a sponsor "may" bring a declaratory judgment action. *Id.* § 262(*l*)(9)(B). And, unlike earlier bills addressing biosimilars, there is no other provision limiting a court's ability to compel compliance with the 180-day notice requirement. *See* Amgen Br. 45. Because the BPCIA does not contain any remedy for failing to comply with the 180-day notice requirement, let alone an "exclusive" one, the UCL is available to provide a remedy for such "unlawful" conduct.

3. *The BPCIA does not preempt state law claims*

"[T]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citation omitted).

Courts find preemption in three circumstances: when there is an "express provision for preemption," "[w]hen Congress intends federal law to 'occupy the field,'" and when state law "conflict[s] with a federal statute." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citation omitted). The BPCIA contains no express preemption provision. Nor does federal patent law preempt the entire field of unfair competition. *See Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1333 (Fed. Cir. 1998) ("[T]here is no field preemption of state unfair competition claims that rely on a substantial question of federal patent law.").

The UCL also does not conflict with or pose "an 'obstacle to the accomplishment and execution'" of federal objectives. *Wyeth*, 555 U.S. at 577 (citation omitted); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996). The Federal Circuit has explained that "[t]he patent laws will not preempt [state-law] claims if they include additional elements not found in the federal patent law cause of action and if they are not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law." *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999). Amgen's state-law UCL claim includes an additional element: economic injury due to the unlawful practice. *See, e.g., Svenson v. Google Inc.*, 65 F. Supp. 3d 717, 730 (N.D. Cal. 2014); *Kwikset Corp. v. Superior Court*, 246 P.3d 877, 885-87 (Cal. 2011). And they offer no "patent-like protection." Nor do they replicate a "federal patent law cause of action" because they turn on the failure to follow statutory procedures, not a period of exclusivity for innovation.

Moreover, as discussed above and explained by Amgen (Br. 46-49), allowing an innovator to enforce the

mandatory BPCIA provisions through UCL claims would further Congress's intent of streamlining patent disputes in advance of product launch, not frustrate it. *See, e.g.*, *Ontiveros v. Zamora*, No. 08-cv-567, 2014 WL 3057506, at *3-4 (E.D. Cal. July 7, 2014) (finding no conflict preemption because UCL claim was consistent with "animating purpose and objectives" of federal law); *Aguayo v. Oldenkamp Trucking*, No. 04-cv-6279, 2005 WL 2436477, at *9-10 (E.D. Cal. Oct. 3, 2005) (same). And it would not require a court to answer any legal question that the BPCIA has delegated to an administrative agency. *Cf. Martinez v. Wells Fargo Home Mortg., Inc.*, 598 F.3d 549, 556 n.8 (9th Cir. 2010) ("regulation of a national bank's adherence to ... regulations is within the exclusive purview of" federal agency); *Snohomish Cty. v. Dynegy Power Mktg., Inc. (In re Cal. Wholesale Elec. Antitrust Litig.)*, 244 F. Supp. 2d 1072, 1078, 1083 (S.D. Cal. 2003) ("Plaintiff's state-law claims ... would inevitably conflict with [federal agency's] exclusive jurisdiction ...."), *aff'd sub nom. Pub. Util. Dist. No. 1 of Snohomish Cty. v. Dynegy Power Mktg., Inc.*, 384 F.3d 756 (9th Cir. 2004). Nor could Sandoz's exclusive-remedy argument establish the necessary conflict for all the reasons discussed above. *See supra* at 22-23.

In sum, there is no basis to find that Amgen's UCL claim is preempted by the BPCIA, which may explain why Sandoz never argued otherwise. The BPCIA does not meet the "high threshold [that] must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act." *Chamber of Commerce of the United States v. Whiting*, 563 U.S. 582, 607 (2011) (citations omitted).

* * *

Because the federal private right of action framework is entirely misplaced here, and because Sandoz has never argued that Amgen's state-law claims are preempted, this Court could and should resolve this case without deciding how a reference product sponsor can enforce the BPCIA's mandatory commands. That is, the Court should hold that Sections 262(*l*)(2)(A) and 262(*l*)(8)(A) are mandatory and that notice of commercial marketing must be given after FDA licensure (as Amgen argues), and remand for the Federal Circuit to determine the proper disposition of the actual claims before it (*i.e.*, California state-law claims) in light of Sandoz's waiver of any preemption argument and the fact that the relief initially requested is now moot.

As a practical matter, the critical point is this: if this Court holds that biosimilar applicants must follow the notice-and-exchange procedures and must give notice of commercial marketing after FDA licensure, that is (presumably) what biosimilar applicants will do—if there is at least the possibility of *some* enforcement mechanism. If a biosimilar applicant nonetheless chooses to completely disregard this Court's holding and flagrantly violate the law, a court can then decide the appropriate enforcement mechanism.

CONCLUSION

The decision of the Federal Circuit should be affirmed in part (as to its finding that the 180-day notice provision is mandatory and must be provided after licensure), reversed in part (as to its finding that the patent-exchange process is optional), and remanded.

Respectfully submitted,

MELISSA ARBUS SHERRY
Counsel of Record
GREGORY G. GARRE
MICHAEL A. MORIN
CASEY L. DWYER
ALEXANDRA SHECHTEL
LATHAM & WATKINS LLP
555 11th Street, NW
Suite 1000
Washington, DC 20004
(202) 637-2200
melissa.sherry@lw.com
Counsel for Amicus Curiae AbbVie Inc.

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ADDENDUM

ADDENDUM A

	Sandoz's Biosimilar of Neupogen[i]	Celltrion's Biosimilar of Remicade[ii]	Apotex's Biosimilar of Neulasta[iii]	Apotex's Biosimilar of Neupogen[iv]	Hospira's Biosimilar of Epogen[v]	Amgen's Biosimilar of Humira[vi]
aBLA filed	05/08/14	08/08/14	10/16/14	12/12/14	12/16/14	11/25/15
aBLA provided	N/A	~10/27/14	12/31/14	03/04/15	03/03/15	02/10/16
Phase One Complaint	10/24/14[vii]	03/06/15	08/06/15	10/02/15	09/18/15	08/04/16
FDA approval	03/06/15	04/05/16	N/A	N/A	N/A	09/23/16
Notice of Comm. Marketing	07/08/14 & 03/06/15	02/05/15[viii]	04/17/15	04/17/15	04/08/15	N/A
Launch	09/03/15	11/28/16	N/A	N/A	N/A	N/A

[i] *See* Compl. ¶¶ 63, 69, *Amgen Inc. v. Sandoz Inc.*, No. 3:14-cv-04741 (N.D. Cal. Oct. 24, 2014); *see also* Sandoz Br. 18-26; License Approval, U.S. FDA, BLA 125553 (Mar. 6, 2015), http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125553Orig1s000ltr.pdf.

[ii] Compl. ¶¶ 89, 123, *Janssen Biotech Inc. v. Celltrion Healthcare Co., Ltd.*, No. 1:15-cv-10698-MLW (D. Mass. Mar. 6, 2015), ECF No. 1; Answer ¶¶ 87, 104, ECF No. 39; Reply in Supp. of Appellants' Mot. to Extend Time for Filing Their Appeal Br. at 3, *Janssen Biotech Inc. v. Celltrion Healthcare Co.*, No. 17-1120 (Fed. Cir. Dec. 7, 2016); Press Announcement, U.S. FDA, *FDA approves Inflectra, a biosimilar to Remicade* (Apr. 5, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm.

[iii] Compl., *Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-61631 (S.D. Fla. Aug. 6, 2015), *consolidated with Amgen Inc. v. Apotex, Inc.*, No. 0:15-cv-62081 (S.D. Fla. Oct. 2, 2015), ECF No. 1; Answer ¶¶ 12, 52, Counterclaims ¶¶ 25, 65, ECF No. 35.

[iv] Compl. ¶ 51, *Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-62081 (S.D. Fla. Oct. 2, 2015), ECF No. 1, *consolidated with Amgen Inc. v. Apotex Inc.*, No. 0:15-cv-61631 (S.D. Fla. Aug. 6, 2015); Consolidated Answer ¶ 12, Counterclaim ¶¶ 28, 81, ECF No. 64.

[v] Compl. ¶¶ 37, 43, 62, *Amgen Inc. v. Hospira, Inc.*, No. 1:15-cv-839 (D. Del. Sept. 18, 2015), ECF No. 1; Press Release, Hospira, Inc., *Hospira Submits New Biologics License Application to U.S. FDA for Proposed Epoetin Alfa Biosimilar* (Jan. 12, 2015), http://www.prnewswire.com/news-releases/hospira-submits-new-biologics-license-application-to-us-fda-for-proposed-epoetin-alfa-biosimilar-300018991.html.

[vi] Compl. ¶¶ 36, 38, *AbbVie Inc. v. Amgen Inc.*, No. 1:16-cv-666 (D. Del. Aug. 4, 2016), ECF No. 1; Answer ¶ 15, ECF No. 13; Press Announcement, U.S. FDA, *FDA approves Amjevita, a biosimilar to Humira* (Sept. 23, 2016), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm522243.htm.

[vii] Note that because Sandoz did not engage in the notice-and-exchange process at all, this was not a phase-one complaint but rather a suit based on state-law claims and a claim for patent infringement under 35 U.S.C. § 271(e)(2)(C)(ii).

[viii] Celltrion's marketing partner Hospira also claimed that commercial-marketing notice was given on March 31, 2014 (prior to the filing of the aBLA), when Celltrion filed a declaratory judgment action against Janssen for patent invalidity. *See* Opp. to Mot. to Dismiss at 22, *Hospira, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-7049 (S.D.N.Y. Oct. 16, 2014), ECF No. 42 (citing Compl. ¶¶ 61, 62, *Celltrion Healthcare Co., Ltd. v. Janssen Biotech, Inc.*, No. 1:14-cv-11613 (D. Mass. Mar. 31, 2014)).